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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,514	10/06/2000	Haruhiko Yokoi	249-118	9035

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EXAMINER

SPECTOR, LORRAINE

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/680,514	Applicant(s) YOKOI ET AL.	
	Examiner Lorraine Spector	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12/23/2002, 3/21/2003 and 4/7/2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-18 is/are pending in the application.
- 4a) Of the above claim(s) 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 10-18 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Part III: Detailed Office Action

Claims 10-15 remain under consideration.

The rejection of Claims 10-15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of applicants amendments.

Restriction Requirement:

Applicant's election with traverse of Invention I, claims 10-15 in Paper No. 8 filed 12/23/02 is acknowledged. The traversal is on the ground(s) that the examination of both groups would not constitute an undue search burden. This is not found persuasive because as stated in the previous Office Action, search burden is established by the separate classification of the claimed inventions. Further, it is noted that a search of Invention II would require search and consideration of areas not required for search of the product itself.

The requirement is still deemed proper and is therefore made FINAL.

Objection to the specification:

The amendment filed 12/23/02, paper number 8, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The incorporation by reference of application serial number 08/765337 is not proper. To the extent that that application contains information which may not be present in the instant specification, such introduction of a new incorporation by reference is an introduction of new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Rejections Over Prior Art:

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-15 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Curtis et al., U.S. Patent Number 5,073,627 in view of Yamasaki et al., EP 0 335 423, de Sauvage et al., Nature 369:533-538, cited by applicants, and Souza, U.S. Patent Number 4,999,291 for reasons cited in the previous Office action, paper number 6 at pages 4-6. Applicants traversal in paper number 8 has been fully considered but is not deemed persuasive.

Applicants argue that the claimed fusion protein differs from that of Curtis et al. In that G-CSF and TPO have two different activities, whereas GM-CSF and IL-3, as disclosed by Curtis et al., have similar activities.

This argument has been fully considered but is not deemed persuasive. Applicants argument ignores the teachings of Souza, also cited in the rejection, which discloses that it is desirable to co-administer G-CSF "in combination with other hematopoietic factors or drugs in the treatment of hematopoietic disorders"; see column 4, lines 52-55. One of ordinary skill in the art knows and appreciates that patients in need of one type of blood cell often need others, that is, that a patient that is undergoing, for example chemotherapy, would be depleted in *both* thrombocytes (platelet producing cells) and lymphocytes (white blood cells) and would benefit from the administration of

proteins that would address both problems. The common activity shared by both G-CSF and TPO is that they are both hematopoietic factors, within the meaning of the Souza disclosure which teaches co-administration of G-CSF with other hematopoietic factors.

At page 5 of the response, applicants argue that the results presented in table 8 are unexpected, in that it would not be expected that the fusion protein would induce expression of CD61 cells (platelets and megakaryocytes) better than mpl ligand alone, and more than twice as great as coadministration of G-CSF and mpl ligand. This argument has been fully considered but is not deemed persuasive for several reasons. First, it is not clear from table 7, found at page 54 of the specification, that equivalent amounts of the active agents were administered: While there is a difference in CD61 levels, it is not a large difference, being approximately three-fold at the lowest dose, and two-fold at the higher doses. As no information is given as to the experimental error, it cannot be determined whether or not the difference is significant. It is noted that the effect, if real, was even smaller in vivo. This degree of effect is not inconsistent with differences in activity due to the mere larger size of the fusion protein (larger proteins can be more stable, and take longer to degrade). As the effect is not dramatic, and is not inconsistent with what would reasonably be expected, the result is nor probative of overcoming the *prima facie* finding of obviousness.

At the penultimate page of the response, applicants allege that the cited references do not disclose or suggest that the fusion protein would retain the activities of its separate components. This is simply erroneous. Curtis teaches the fusion of two hematopoietic proteins, IL-3 and GM-CSF, *for the purpose of combining the two activities in a single molecule*. The Examiner does not understand applicants implication that the result would be expected to be otherwise.

Advisory Information:

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the

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THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

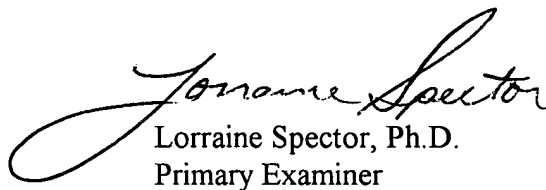
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.


Lorraine Spector, Ph.D.
Primary Examiner

LMS
09/680514.2
6/11/03